

February 25, 2005

Dr. Ronald Joiner
Manager, Global Toxicology
General Electric Company
One Plastics Avenue
Pittsfield, MA 01201

Dear Dr. Joiner:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 5,5'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[2-methyl-1H-isoindole-1,3(2H)-dione] (Bisphenol A Bisimide, CAS No. 54395-52-7), posted on the ChemRTK HPV Challenge Program Web site on March 2, 2004. I commend General Electric Company – Plastics (GE Plastics) for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. EPA agrees with the test plan for these endpoints and recommends using the Level III fugacity model.
2. Health Effects. Adequate data are available for repeated-dose and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA agrees with the test plan for addressing the reproductive and developmental toxicities. The submitter needs to include the range finding results from the proposed reproductive/developmental screening test in the acute toxicity discussion.
3. Ecological Effects. EPA agrees with the test plan for these endpoints.

The submitter needs to verify that page 2 of the test plan is intentionally blank and that no information has been omitted.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that GE Plastics advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure
cc: W. Penberthy
M. E. Weber